## REMARKS

### Amendments

Per the examiner's request, applicant has reviewed and updated references to U.S. patent documents in the specification. Other amendments to the specification correct grammatical informalities.

The abstract is amended to provide references to host cells and methods of making purified antibodies, as described throughout the disclosure.

New claims 98 and 103 include the language of claims 70 and 72 and additionally recite that the host cell is capable of expressing and secreting an immunologically active chimeric anti-CD20 antibody. Claim 103 further recites that the host cell comprises promoter and signal sequences. Such host cells are described, *e.g.*, at pages 20-21 of the specification. New claims 99 and 104 track the language of original claim 71.

New dependent method claims 100-102 and 105-107 parallel claims 76-78. As these claims correspond to a nonelected invention, they are marked "new–withdrawn" with the expectation that the examiner will consider them withdrawn under 37 C.F.R. § 1.142(b).

The amendments add no new matter to the disclosure.

### Sequence listing

A substitute sequence listing accompanies this paper. The information fields in the sequence listing are revised to reflect the concurrently-filed amendment to the inventorship. Except for this revision, the new sequence listing is identical to the sequence listing it replaces. Thus, applicant submits that this amendment adds no new matter.

A computer-readable copy of the sequence listing is filed with this amendment via the Office's electronic filing facility. In compliance with 37 C.F.R. § 1.821(e), the undersigned states that the paper and computer-readable copies of the sequence listing are identical.

**Abstract**

The abstract is amended to provide references to host cells and methods of making purified antibodies, such as those to which the pending claims are directed. Applicant believes that this amendment addresses the basis for the objection stated at page 2 of the Office action. Accordingly, applicant requests that the examiner withdraw the objection.

**Inventorship**

Consistent with facts stated in connection with a petition to correct inventorship that was submitted in parent application serial no. 08/149,099, applicant is filing concurrently a request under 37 C.F.R. § 1.48(b) to amend the inventorship in this application. Because no claims to the invention of John E. Leonard remain in this application, his name is deleted from the inventive entity of the present application.

**Rejection under 35 U.S.C. § 112, first paragraph**

The Office rejects claims 70-75 under the written description requirement of § 112, first paragraph. Applicant respectfully traverses the rejection.

First, the Office suggests that if there is no explicit description of membrane-bound antibodies, there is "no support" for claims 70 and 72. The antibodies recited in the claims, however, are "immunologically active chimeric anti-CD20 antibod[ies]." The structural and functional properties of antibodies generally, and chimeric and immunologically active anti-CD20 antibodies in particular, are discussed at length in the specification, *e.g*, at pages 11-13 and 19-23. Thus, the written description provides extensive and detailed support with respect to the nature of the recited antibodies for the invention as claimed. The written description is more than sufficient to demonstrate to one of skill that the inventors invented the subject matter recited in the claims.

Second, the Office construes the claims to "encompass host cells that express the [recited] nucleic acid … in the absence of additional regulatory nucleic acid sequences required for secretion … ." Because the Office alleges that there is no descriptive support for "host cells

that only contain the specific nucleic acid recited in the claims," it finds that the claims are directed to new matter.

In fact, the disclosure provides a written description of both host cells that are used to produce secreted antibodies, and those that are not. For example, the CHO and SP2/0 transfectomas comprising the deposited expression vector are used to produce secreted antibodies. The written description also extends to host cells that comprise the recited nucleic acid sequences, but do not necessarily secrete antibody polypeptides. *See*, *e.g.*, the paragraph bridging pages 19-20, describing host cells and methods for making chimeric antibodies that do not require that the antibodies be secreted from the host cells. Also, the *E. coli* cells deposited as ATCC 69119, which do not necessarily secrete antibodies, are host cells encompassed by claim 70. Applicant also notes that related application serial no. 08/147,696, now U.S. Patent No. 5,648,267, which is expressly incorporated by reference in the present application, describes cells comprising cloning vectors that do not necessarily express or secrete the polypeptides that the vectors encode. *See* the '267 patent at, *e.g.*, the paragraph bridging cols. 1-2. As that patent notes, such cloning vectors and host cells comprising them were well known to those skilled the art. Thus, the Office's characterization of the written description is not accurate as it reads into the disclosure a requirement for sequences capable of directing the secretion of antibodies in every host cell according to claims 70-75.

Moreover, the Office's interpretation of the claims is not consistent with what the claims recite. The Office states that

> the claims encompass host cells that express the nucleic acid recited in the claims in the absence of additional regulatory nucleic acid sequences required for secretion of the antibody … . The claims encompass host cells that only contain the specific nucleic acid recited in the claims … .

But none of the claims recites a limitation that affirmatively excludes regulatory sequences or any other host cell component. Furthermore, independent claim 70 contains no language regarding the capacity to express or secrete immunoglobulin polypeptides. It is drawn to host cells comprising the recited nucleic acid sequences, without regard to additional functional properties they may have. One of skill in the art would understand that the term "host cell," as used in the disclosure, necessarily implies the presence of the molecular or genetic features that

allow the recited nucleotide sequences to function biologically in the manner recited in the respective claims.

In addition to relying on incorrect assessments of the content of the disclosure and the requirements of the claims, the Office's analysis of compliance with the written description requirement relies upon an improper understanding of § 112, first paragraph. The Office incorrectly suggests that claims 70 and 72 are not supported with respect to the scope of recited antibodies because, it believes, the disclosure does not provide a literal description of every species of antibody to which the claims relate. In this case, the claimed invention is generic with respect to the nature of the recited antibody, except for the specified variable domain sequences.

The law does not require patent applicants to provide what the Office considers to be missing. "A specification may, within the meaning of 35 U.S.C. § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1998) (citations omitted); *see also* M.P.E.P. § 2163. Furthermore, the Office has cited no evidence to indicate that one of skill at the time the application was filed would have considered the unqualified term "antibody," as employed in the written description, to exclude any particular known type of antibody, or that the term was used in a manner contrary to any art-recognized meaning. Thus, the written description supports the invention of claims 70 and 72 in terms that are commensurate with the claimed subject matter. Applicant submits that the first aspect of the rejection is not well founded.

The Office also concludes improperly that the written description provides inadequate support for the recited host cells. The Office believes that the claims should recite additional elements that are described in some of the examples. However, "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics … [such as] *functional characteristics when coupled with a known or disclosed correlation between function and structure,* or some combination of such characteristics.'" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (2002) (quoting and endorsing application of the PTO's Written Description Guidelines; emphasis in original); *see also* M.P.E.P. § 2163, subsection II.3.a.ii. In this case, the

features of host cells having the recited functions are well known in the art. Thus, the recitation of claim elements that have functional aspects, such as "host cell" (claim 70) or "capable of producing an immunologically active chimeric anti-CD20 antibody" (claim 72), is supported by the language and examples set forth in the written description. Moreover, the claims refer to the specific structures (*i.e.*, the particular nucleic acid sequences) that, in addition to such well-known features of host cells, correspond to host cells that meet the requirements of the claims. Accordingly, the claims meet the requirements of § 112.

Finally, it is improper for the Office to conclude that the claims do not comply with the written description requirement because they do not recite every feature of particular illustrative examples described in the specification. The Office appears to consider that the claims must be compared to the disclosure for the recitation of some perceived "essential" element(s) of such examples. Such an analysis, however, has been flatly rejected by the Federal Circuit. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prod., Inc.*, 291 F.3d 1317, 1323, 62 USPQ2d 1846, 1849 (Fed. Cir. 2002). The Office has identified no evidence to support the view that one of skill in the art, upon reading the present disclosure, would consider that the written description does not show that the inventors invented the subject matter of the invention as claimed. *See Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

Because the invention as claimed is fully supported by the written description as filed, applicant requests that the examiner withdraw the rejection of claims 70-75.

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**Conclusion**

Applicant believes that this reply fully responds to the outstanding Office action.

Applicant requests that the Office withdraw the outstanding objections and rejections and indicate that all of the pending claims are allowable. Applicant reiterates the request that the restriction requirement between the elected product claims and the dependent method claims be withdrawn upon a finding that the product claims are allowable.

Respectfully submitted,

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